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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,496

12/05/2003

Punam K. Saha

P-2944

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67283 7590 08/23/2007

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EXAMINER

KRASNIC, BERNARD

ART UNIT

PAPER NUMBER

2624

MAIL DATE

DELIVERY MODE

08/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/728,496

**Applicant(s)**

SAHA ET AL.

**Examiner**

Bernard Krasnic

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. The amendment filed 7/18/2007 have been entered and made of record.

2. In response to the amendments filed on 7/18/2007:

The "Objections to the abstract" have been entered and therefore the Examiner withdraws the objections to the abstract.

The "Objections to the claims" have been entered and therefore the Examiner withdraws the objections to the claims.

The "Claim rejections under 35 U.S.C. 112, second paragraph" have been entered and therefore the Examiner withdraws the rejections under 35 U.S.C. 112, second paragraph.

The "Claim rejections under 35 U.S.C. 101" are still maintained for claims 25-30.

3. Applicant's arguments with respect to claims 1-24 and 29 have been considered but are moot in view of the new ground(s) of rejection.

4. Applicant's arguments filed 7/18/2007 have been fully considered but they are not persuasive.

The Applicant alleges, "Response to the Rejection under 35 U.S.C. 101 ..." in page 7, and states respectively that the claims have been amended accordingly to demonstrate the production of a "useful, concrete and tangible result" and therefore the 35 U.S.C. 101 rejections should be withdrawn. The Examiner agrees that amended

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claims 1-21 and 29 do now propose a useful, concrete and tangible result because of the amended limitation "compiling a report or revised image based upon the FDT calculations" that is incorporated into the independent claims 1, 17, and 29. Therefore the Examiner withdraws the 35 U.S.C. 101 rejections toward "No Practical Application" for claims 1-21 and 29; however as will be seen in the rejections below, this amended limitation is considered to be new matter. However claims 25-28 and 30 still merely manipulate data or merely solves a mathematical problem without a limitation to a Practical Application because no amended limitation has been incorporated into independent claims 25 and 30. Also, the Examiner appreciates the amendment of incorporating the computer into claims 25-30, but the Examiner needs to stress the importance of following the USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005) which require specific claim language when dealing with computer implemented systems and programs. The Examiner suggested an example for claim limitation changes, but the Applicant has chosen to ignore these suggestions. Therefore the 35 U.S.C. 101 rejections are still maintained toward claims 25-30 for not embodying the program and computer based system in proper computer readable medium language as will be discussed below.

The Applicant alleges, "The reference cited by the Examiner is misrepresented ..." in pages 7-8, and states respectively that the publication date is not June 2002 but November 27, 2002. The Examiner disagrees and has incorporated the "PORTAL, ACM Digital Library" reference data which clearly shows that the publication date for the

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Non-Patent Literature document "Fuzzy distance transform: theory, algorithms, and applications" is indeed June 2002.

The Applicant alleges, "Response to the Rejection under 35 U.S.C. 102(a) ..." in pages 7-9, and states respectively that the Non-Patent Literature document "Fuzzy distance transform: theory, algorithms, and applications" incorporated the current applications inventors as the lead authors and that the third author Gomberg was not the lead author and therefore the 35 U.S.C. 102(a) rejection should be withdrawn. However, 35 U.S.C. 102(a) clearly states:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Since Gomberg is a third author who is not an inventor of the current application and the art reference Non-Patent Literature document "Fuzzy distance transform: theory, algorithms, and applications" is published prior to the filing of the Applicants application, a 35 U.S.C. 102(a) rejection is definitely appropriate. Therefore, the rejections are maintained.

The Applicant alleges, "As to the references by the Examiner ..." in page 9, and states respectively that the Applicant cannot find a reference to a specific rejection based upon that statute. 35 U.S.C. 112, 6<sup>th</sup> paragraph discloses as stated in the MPEP:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Therefore, the Examiner has incorporated 35 U.S.C. 112, 6<sup>th</sup> paragraph not as a rejection but as an identifier to show that the claim language invokes this means plus function language.

The Applicant alleges, "Response to the Rejection under 35 USC 103(a) ..." in pages 9-11, and states respectively that the secondary reference of Gomberg's dissertation is not appropriate prior art because it is not Gomberg's work and because there is no motivation to combine because the thesis dissertation does not disclose Fuzzy Distance Transforms. However the Examiner firstly disagrees because the dissertation was published by the different author Gomberg, prior to the Applicants filing date. Secondly, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gomberg (Dissertation) states the motivation is to indicate optimal treatment to restore bone strength and monitor therapy response. In response to applicant's argument that Gomberg is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Gomberg is an author to both references and both references do talk about analyzing bone regions in medical images which show that they are in analogous arts. Therefore, the rejections are maintained.

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The Applicant alleges, "The Examiner has rejected claims 22-24 ..." in pages 9-10, and states that the Gomberg reference fails to suggest the limitation of selecting a therapy based on the diagnosis or evaluation. However, the Gomberg dissertation states, "the information derived from such a device could indicate optimal treatment to restore bone strength and monitor therapy response" in page 3 which clearly shows selecting the optimal treatment from some type of diagnostic information and monitoring the response afterward. Therefore, the rejections are maintained.

### ***Claim Objections***

5. Claims 5 and 21 are objected to because of the following informalities:

Claims 5 and 21, line 2 respectively: "along the medial" should be -- along a medial --.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

Claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a claim reciting a signal encoded with functional descriptive material falls within any of the categories of patentable subject matter set forth in Sec. 101.

... a signal does not fall within one of the four statutory classes of Sec. 101.

... signal claims are ineligible for patent protection because they do not fall within any of the four statutory classes of Sec. 101.

Claim(s) 30 is/are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim(s) 30 defines "a signal-bearing medium" in line 3 with descriptive material. While "functional descriptive material" may be claimed as a statutory product (i.e., a "manufacture") when embodied on a tangible computer readable medium, a signal-bearing medium embodying that same functional descriptive material is neither a process nor a product (i.e., a tangible "thing") and therefore does not fall within one of the four statutory classes of § 101. Rather, "signal" is a form of energy, in the absence of any physical structure or tangible material. The phrase "signal-bearing" should be deleted.

Appropriate correction is required.

8. The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Section IV.C, reads as follows:

While abstract ideas, natural phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, natural phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of section 101, the claim must be considered as a whole to determine whether it is for a particular application of an abstract idea, natural phenomenon, or law of nature, rather than for the abstract idea, natural phenomenon, or law of nature itself.

For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomenon. Diehr, 450 U.S. at 187, 209 USPQ at 8 ("application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); Benson, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it "has no substantial practical application").



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To satisfy section 101 requirements, the claim must be for a practical application of the Sec. 101 judicial exception, which can be identified in various ways:

The claimed invention "transforms" an article or physical object to a different state or thing.

The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

Further, claim(s) 25-28 and 30 is/are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 25-28 and 30 recites functional descriptive material on a computer readable medium. However, the program/algorithm itself merely manipulates data or an abstract idea, or merely solves a mathematical problem without a limitation to a practical application. A practical application exists if the result of the claimed invention is "useful, concrete and tangible" (with the emphasis on "result")(Guidelines, section IV.C.2.b). A "useful" result is one that satisfies the utility requirement of section 101, a "concrete" result is one that is "repeatable" or "predictable", and a "tangible" result is one that is "real", or "real-world", as opposed to "abstract" (Guidelines, section IV.C.2.b)). Claim(s) 25-28 and 30 merely manipulate data without ever producing a useful, concrete and tangible result because it essentially calculates the fuzzy distance transform (FDT) which is basically a mere manipulation of data or a mere solution to a mathematical problem with no practical application, whereas claims 22-24 are using the results of the computer implemented FDT process to further select and administer a therapy which definitely is a limitation toward a practical application.

In order to for the claimed product to produce a "useful, concrete and tangible" result, recitation of one or more of the following elements is suggested:

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- The manipulation of data that represents a physical object or activity transformed from outside the computer.
- A physical transformations outside the computer, for example in the form of pre or post computer processing activity.
- A direct recitation of a practical application;

Applicant is also advised to provide a written explanation of how and why the claimed invention (either as currently recited or as amended) produces a useful, concrete and tangible result.

Appropriate correction is required.

9. Further, claim(s) 25-28 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 25-28 and 30 are drawn to functional descriptive material NOT claimed as residing on a computer readable medium using proper format limitation language. MPEP 2106.IV.B.1(a)

(Functional Descriptive Material) states:

"Data structures not claimed as embodied in a computer-readable medium are descriptive material per se and are not statutory because they are not capable of causing functional change in the computer."

"Such claimed data structures do not define any structural or functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized."

Claim(s) 25-28 and 30, while defining a "programming based algorithm" and a "computer-readable signal-bearing medium", does not define a "computer-readable medium" and is thus non-statutory for that reasons. A "programming based algorithm" and a "computer-readable signal-bearing medium" can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The examiner suggests amending the claim to embody the program on "computer-readable medium" in order to make the claim statutory. The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005) have specific guidelines on how to draft computer readable implemented claims and therefore the Examiner has suggested the following:

Re Claim 25: "A dynamic programming-based algorithm operating on a computer to compute" in lines 1-2 should be -- A computer readable medium encoded with computer readable instructions for computing --. "a fuzzy subset on computer readable medium" in line 3 should be -- a fuzzy subset --.

Re Claims 26-28: "The algorithm operating on a computer of claim" in line 1 should be -- The computer readable medium of claim --.

Re Claim 29: The limitation before amendment "A system for analyzing digital images by a fuzzy distance transform-based computational method comprising:" did not consist of any computer readable medium 35 U.S.C. 101 issues, but does now. "A computer-based system" should be -- A system --. This suggestion is offered because the Examiner believes that the Applicant initially wanted a system claim and not a computer implemented claim for claim 29 but might have misunderstood the initial

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rejection to claim 29 for No Practical Application which was corrected by the amended limitation "means for reporting same or providing ...".

Re Claim 30: "A computer-based device for analyzing digital images by a fuzzy distance transform-based computational method comprising: a computer-readable signal-bearing medium;" is suggested to be -- A computer readable medium encoded with computer readable instructions for analyzing digital images by a fuzzy transform-based computational method comprising: --.

"In contrast, a claimed computer-readable medium encoded with the data structure defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure's functionality to be realized, and is thus statutory." - MPEP 2106.IV.B.1(a)

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1, 17 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. The amended limitation "compiling a report or revised image based upon the FDT calculation" is not specifically disclosed in the specification and therefore is considered as new matter.

Claims 2-16 are dependent upon claim 1.

Claims 18-24 are dependent upon claim 17.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 1-21 and 25-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Gomberg ("Fuzzy distance transform: Theory, algorithms, and applications" – Computer Vision and Image Understanding – June 2002, vol. 86, pages 171-190, as applied in previous Office Action).

Re Claim 1 [as best understood by the Examiner]: Gomberg discloses a fuzzy distance transform-based computational method / FDT algorithms for analyzing digital images / medical images defining a volumetric region / 3D or cubic spaces of an object from an image / medical image comprising: (a) obtaining an image of the targeted object / digital

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object; (b) finding a plurality of points in the image to generate a fuzzy subset and calculating a fuzzy distance transform (FDT) of the fuzzy subset (see page 171-172, paragraph "This paper describes the theory and algorithms ..."); and (c) compiling a report / FDT image or revised image based upon the FDT calculations / quantified thickness of the vascular structures (see Figs. 4c and 5c, page 189, paragraph 1, pages 173, last sentence of paragraph "In this paper, we develop ...").

Re Claim 17 [as best understood by the Examiner]: Gomborg discloses a fuzzy distance transform-based computational method / FDT algorithms for evaluating or diagnosing bone disease / fracture in a subject / human by analyzing digital images / medical images defining at least one volumetric region / 3D or cubic spaces of bone / trabecular bone from or in the subject, the method comprising: (a) obtaining an image of targeted bone region / digital image of trabecular bone; (b) finding a plurality of points in the image to generate a fuzzy subset and calculating a fuzzy distance transform (FDT) of the fuzzy subset (see page 171-172, paragraph "This paper describes the theory and algorithms ...", Fig. 7, pages 186-187, paragraph "The second example of thickness ..." and "A further demonstration of the effectiveness ..."); and (c) compiling a report / FDT image or revised image based upon the FDT calculations / quantified thickness of the vascular structures (see Figs. 4c and 5c, page 189, paragraph 1, pages 173, last sentence of paragraph "In this paper, we develop ...").

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Re Claim 25: Gomberg discloses a dynamic programming-based algorithm operating on a computer / programming based algorithm to compute fuzzy distance transform (FDT) by means of a plurality of points in an image of a target object / digital image used to generate a fuzzy subset on a computer readable medium, and to calculate the FDT of the fuzzy subset, said FDT terminating in a finite number of steps (see page 171-172, paragraph "This paper describes the theory and algorithms ...").

As to claim 29 [as best understood by the Examiner], the claim is the corresponding means plus function system claim to claim 1 respectively. The discussions are addressed with regard to claim 1.

The limitations, as recited in claim 29, "means for obtaining" in line 3, "means for defining" in line 4, "means for finding" in line 5, and "means for calculating" in line 6, and "means for reporting same or for providing" in line 7 invoke 35 U.S.C. 112, sixth paragraph.

Re Claim 30 [as best understood by the Examiner]: Gomberg discloses a computer-based device for analyzing digital images by a fuzzy distance transform-based computational method / FDT algorithm comprising: a computer-readable signal-bearing medium; means in the medium for acquiring or reading a 3D image / medical image of at least one volumetric region / 3D or cubic space of a target object / digital object; means in the medium for identifying a plurality of points in the image to generate a fuzzy subset; and a means in the medium for calculating the fuzzy distance transform (FDT)

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of the fuzzy subset (see page 171-172, paragraph "This paper describes the theory and algorithms ...", the programmed algorithm is obviously presented for computing on a computer).

The limitations, as recited in claim 30, "means for acquiring" in line 4, "means for identifying" in line 6, and "means for calculating" in line 8 respectively invoke 35 U.S.C. 112, sixth paragraph.

Re Claim 2: Gomberg further discloses the calculating step comprises assigning to a point in the fuzzy subset its respective fuzzy distance from a complement of a support of the fuzzy subset (page 171, paragraph "This paper describes the theory and algorithms ...", lines 16-17).

Re Claim 3: Gomberg further describes the support comprises a set of all points in the fuzzy subset with a value greater than or equal to a support value (page 171, paragraph "This paper describes the theory and algorithms ...", lines 11-13).

Re Claim 4: Gomberg further discloses the FDT is in digital cubic space (page 171, paragraph "This paper describes the theory and algorithms ...", line 18).

Re Claim 5: Gomberg further discloses the step of sampling FDT values along the medial axis of the support of the fuzzy subset to estimate regional target object / digital



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object thickness distribution (see page 182, Fig. 3 caption, page 187, Fig. 7 caption, page 184, Section – 4.1 Computation of Thickness).

Re Claim 6: Gomberg further discloses the target object / digital object comprises bone marrow space, cortical bone, blood vessels or lung airways (see page 172, Section – INTRODUCTION, lines 14-16).

Re Claim 7: Gomberg further discloses the FDT is computed in digital cubic space of resolution of target object / digital object thickness or smaller (see page 172, Section – INTRODUCTION, line 9).

Re Claim 8: Gomberg further discloses the target object / digital object is in or from an animal or human subject / human trabecular bone (see Fig. 7).

Re Claim 9: Gomberg further discloses the image is obtained by magnetic resonance / MR or computed tomography / CT (see Figs. 6 and 7, page 186, paragraph “The second example of thickness ...”, paragraph “A further demonstration ...”).

Re Claim 10: Gomberg further discloses the FDT values are sampled along a medial axis directly computed from the fuzzy subset (see page 182, Fig. 3 caption, page 187, Fig. 7 caption, page 184, Section – 4.1 Computation of Thickness).

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Re Claim 16: Gomberg further discloses applying one or more additional steps consisting of skeletonizing, feature extracting; analyzing morphological or shape-based object, computing regional object depth; calculating average or regional object thickness distribution; and local scaling (see page 172, Section – INTRODUCTION, lines 9-11).

As to claims 11-15, the discussions are addressed with respect to claims 4 and 6-9.

As to claims 18-21, the discussions are addressed with respect to claims 2-5.

As to claims 26-28, the discussions are addressed with respect to claims 2-4.

The limitation “means for assigning” in line 1 of claim 26 invokes 35 U.S.C 112, sixth paragraph.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gomberg (“Fuzzy distance transform: Theory, algorithms, and applications”, as applied in previous Office Action) in view of Gomberg (“In vivo magnetic resonance based

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virtual bone biopsy" - Dissertation, as applied in previous Office Action). The teachings of Gomberg ("Fuzzy distance transform: Theory, algorithms, and applications") have been discussed above.

However, Gomberg ("Fuzzy distance transform: Theory, algorithms, and applications") fails to disclose or fairly suggest selecting a therapy based on the diagnosis or evaluation.

Gomberg (Dissertation), as recited in claim 22, discloses selecting a therapy based on the diagnosis or evaluation of bone disease in the subject (see Chapter 1, pages 1-3, "indicate optimal treatment to restore bone strength and monitor therapy response").

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gomberg's ("Fuzzy distance transform: Theory, algorithms, and applications") evaluating and diagnosing the bone fracture method using Gomberg's (Dissertation) teachings by including the ability to select and administer therapy to the fracture while monitoring the progression or regression of the bone fracture in order to have a possible noninvasive structural analysis of trabecular bones (see Gomberg [Dissertation], Chapter 1, page 3, paragraph 2).

Re Claim 23: Gomberg (Dissertation) further discloses administering said therapy to the subject (see Chapter 1, pages 1-3, "indicate optimal treatment to restore bone strength and monitor therapy response").

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Re Claim 24: Gomberg (Dissertation) further discloses monitoring a progression or regression of bone disease in the subject, during or at one or more times after administering said selected therapy (see Chapter 1, pages 1-3, "indicate optimal treatment to restore bone strength and monitor therapy response").

### ***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Krasnic whose telephone number is (571) 270-

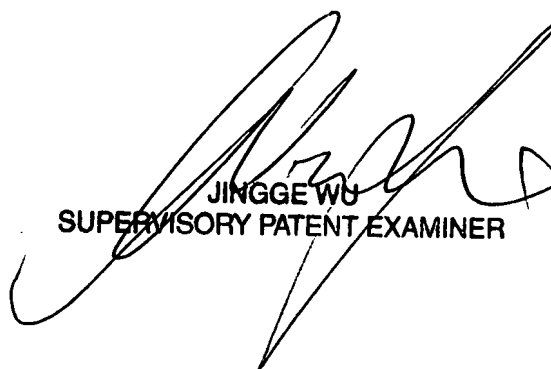
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1357. The examiner can normally be reached on Mon-Thur 8:00am-4:00pm and every other Friday 8:00am-3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jingge Wu can be reached on (571) 272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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August 17, 2007

  
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